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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,022	09/17/2003	Dennis M. Klinman	4239-66899	7954

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NATIONAL INSTITUTES OF HEALTH  
OFFICE OF TECHNOLOGY TRANSFER  
6011 EXECUTIVE BLVD SUITE 325  
ROCKVILLE, MD 20852-3804

EXAMINER
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HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-5, 7-21 and 23-24, drawn to a method of increasing an immune response via administering an immunostimulatory D oligodeoxynucleotide, are classified in class 541, subclass 44.
- II. Claim 22, drawn to a method of increasing an immune response via administering an immunostimulatory K oligodeoxynucleotide or SEQ ID NO:20, is classified in class 514, subclass 44.

Claims 1, 6 and 25 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 6 and 25. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the

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claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the K and D oligonucleotides differ in both structure and function as disclosed by the specification on pages 22-23. Briefly, the K oligonucleotides stimulate B cell proliferation and the production of IL-6 in contrast to the D oligonucleotides which lead to different cellular effects, such as stimulating the release of cytokines from cells. Structurally, as disclosed by the specification on page 22, K oligonucleotides share specific characteristics that differ from those of D oligonucleotides. Further, the specification does not disclose a combined use of K and D oligonucleotides. Because of the reasons above, Inventions I and II are patentably distinct.

### ***Election of Species***

**Following the election of Invention I, Applicant is further required to elect one of the following species below.**

This application contains claims directed to the following patentably distinct species: oligodeoxynucleotides SEQ ID NOs: 1-16 and 22-98. The species are independent or distinct because the species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent structurally different oligodeoxynucleotides. Therefore, where structural identity is required, such as for inducing a particular immune response, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

### **Conclusions**


Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

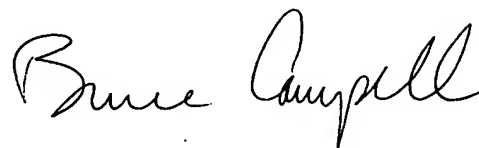
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michelle Horning  
Patent Examiner



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